DECISION MEMO

THE WHITE HOUSE

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MEMORANDUM FOR THE PRESIDENT

FROM: NANCY-ANN DePARLE
SUSAN SHER

SUBJECT: Information on Medical Malpractice Reform Options

The purpose of this memorandum is to provide information on medical malpractice reform options, some of which have received bipartisan support on the Hill in recent years. In view of your repeated rejection of caps on malpractice damage awards, this memorandum does not include proposals to impose caps on non-economic damages.[1] We first provide a brief overview of the legislative landscape and then present information on five options. Because of your interest in the "safe harbor" approach, we have included additional information on this option. The five options discussed in this memorandum include:

1. Safe Harbor: Making Adherence to Evidence-Based Guidelines the Presumptive Standard of Care
2. Early Disclosure of Medical Errors and Mediation (MEDiC)
3. Pre-Trial Administrative Screening Panels
4. Alternative Dispute Resolution
5. Health Courts/Expert Panels

Although each of these proposals has promise, few of them have been subject to substantial testing and evaluation. It is therefore debatable whether and to what extent any one proposal is likely to change clinical practice, lower malpractice premiums, reduce litigation costs, and be viewed as transformational. For that reason, we recommend state-level demonstrations of the proposals as a first step. This approach would provide federal support to states through bonuses or demonstration grants for a variety of reform options. This "states-as-laboratories" proposal resembles the approach taken in several malpractice bills in Congress. It also provides maximum flexibility for states to adopt systems that work best for them from among several options and an opportunity to further study what works in this area. The American Medical Association has recommended this demonstration project approach in meetings with your staff, and they have also indicated that they favor MEDiC-like proposals.

[1] Evidence has shown that caps reduce average damage awards by 20 percent to 30 percent but do not decrease the frequency of medical malpractice claims. Although some argue that caps may reduce the growth of malpractice premiums, there is no evidence that they improve quality of care or reduce health care costs. Finally (and not surprisingly), caps appear to adversely affect the most severely injured patients.

I. Political Landscape

As in the past, there continues to be appetite for medical malpractice reform among Republicans and opposition among most Democrats in Congress. Overall, if the White House wants even modest medical malpractice reforms to be part of health reform, the Administration will need to play a leadership role. In the Senate, Majority Leader Reid has made it clear that he opposes any medical malpractice reform, creating a difficult environment for Democrats to step forward. Senator Baucus is also concerned about the difficulty of making medical malpractice reform part of health care reform in the current environment. Senate Republicans continue to press for caps. Senator Durbin is not working on an affirmative proposal, but if Republicans offer an amendment, he will be prepared to fully engage in the debate. With all of the other major issues to be tackled, the Committees are hesitant to address this issue. There are some bipartisan proposals which have not advanced far; the Wyden-Bennett health reform bill includes fairly aggressive medical malpractice reform provisions, and Senators Baucus and Enzi have co-sponsored a bill that Senator Enzi offered and withdrew (to avoid being voted down) in the HELP Committee last week when offered as an amendment. Senators Lincoln and Kerry have stated privately that they would be willing to consider some reforms, and Senator Carper has communicated more directly that he would be interested in working with the White House on a proposal.

In the House, the Chairs of the three Committees with jurisdiction over health reform have concerns about bringing any policy on medical malpractice reform into the mix. Specifically, Chairman Waxman has been the most vocal in raising concerns with the White House. Stemming from his experience in California, he has very strong substantive concerns regarding any efforts that will be perceived as limiting a patient's legal rights to damages for negligence. In terms of process, all three Committee Chairs have concerns that trying to tackle medical malpractice reform in the context of health reform would bring an additional Committee's jurisdiction into the mix (House Judiciary Committee). The Chairs worry that Rep. John Conyers, Chairman of the House Judiciary Committee, would potentially try to use that leverage to push his own single-payer bill, which could significantly delay progress on the health reform legislation.

II. Information on Medical Malpractice Reform Options

1. Safe Harbor: Making Adherence to Evidence-Based Guidelines the Presumptive Standard of Care

Under this approach, federal law would endorse a national set of clinical practice guidelines (the Agency for Healthcare Research and Quality (AHRQ) guidelines, which are further discussed below, could be a starting point) and offer physicians some sort of a "safe harbor." Although the strength of the "safe harbor" could range from absolute immunity to mere "evidence" of non-negligence, a more balanced proposal would offer physicians a "rebuttable presumption of non-negligence," which a plaintiff could overcome either by a preponderance of the evidence or clear and convincing evidence. Under one version of this approach, plaintiffs also would be able to make "offensive" use of the guidelines. Specifically, a physician's failure to adhere to the guidelines – while not constituting *per se* evidence of negligence – would create a rebuttable presumption of negligence, unless the physician explained his or her reasons for

departure from the guidelines in a written, contemporaneous statement shared with the patient in advance of or (if advance notice is not practicable) soon after the departure from the guidelines.

Federal law, in addition to endorsing or adopting a national set of clinical practice guidelines, could use one of three possible approaches to achieve such a "safe harbor":

- Federalized Standard of Care: Federal law could simply codify the defensive and/or offensive safe harbor as outlined above, thus federalizing the standard of care in state law medical malpractice claims and effectively preempting a key element of such state law claims. To avoid raising the specter of creating "federal question" jurisdiction and thus potentially inundating federal courts with state law medical malpractice cases, any proposal to federalize the standard of care should make clear that Congress did not intend establishment of this standard to create federal jurisdiction over claims that would otherwise be resolved in state court. (We have asked DOJ's Office of Legal Counsel to confirm that such a proposal would not inadvertently flood the federal courts with these claims.)

- Federal Incentives for State Law Creation of Safe Harbor: Federal law could condition the grant of certain health-related financial assistance to states that incorporate into law a safe harbor provision for medical malpractice claims arising from adherence to the national set of clinical practice guidelines adopted by Congress. This approach would raise fewer federalism-based concerns (depending on the nature of the conditioned financial assistance) and also promote state experimentation and variations while national guidelines are refined. However, this may lead to uneven incorporation of national guidelines and thus have only modest effect on physician behavior.

- Federal Defense to State Law Medical Malpractice Claims: Congress could provide a federal defense to any state law medical malpractice claim and disclaim creation of federal court jurisdiction for state law medical malpractice claims. The mere creation of a federal defense would likely avoid an inundation of medical malpractice actions to federal courts. In order to allow or encourage offensive use of the guidelines as well, this approach could be coupled with federal incentive grants to states that adopt a safe harbor provision in state law, as outlined in the bullet above.

Evidence: The safe-harbor approach has not been used in practice except in some isolated circumstances with limited instructional value.

Legislative Efforts: Wyden-Bennett "Healthy Americans Act" (This bill provides incentives to states for specific reforms, including the application of a presumption of reasonableness if a defendant establishes that he followed accepted clinical practice guidelines. The presumption can be rebutted by a preponderance of the evidence.)[2]

Pros of "Safe Harbor" Approach:
- Avenue to enable the development and organization of guidelines in order to promote best practices
- Could induce physician behavioral change to improve clinical practice and follow established guidelines so as to foster "best practice" cost-effective medicine

[2] Additionally, several bills in 1993 included a variety of medical malpractice proposals tied to evidence-based guidelines.

- Could reduce "defensive medicine"[3] since unnecessary procedures would not be directed by the guidelines
- Likely to have the support of the physician community and to provide a sense of protection against baseless lawsuits, particularly if physicians are given a leading role in the development and endorsement of the guidelines

Cons of "Safe Harbor" Approach:

- Would have uncertain effect on malpractice premiums or litigation and could merely shift the legal debate (and costly battle of experts in malpractice cases) to which clinical guidelines are applicable and whether those guidelines were followed. (Note that if complying with the guidelines is merely a rebuttable presumption, litigation over the standard of care will still occur.)
- Could take years to develop, as it will take time to set up a system to create, disseminate, update, and endorse guidelines in particular areas
- May require detailed and expansive federal guidelines for medical care, which could be subject to regulatory challenge and play into the suggestion that the federal government is telling physicians how to treat patients (and urging them to ration care)
- Federalizing a defense to state law could encounter strong objections from trial lawyers
- Fundamental difficulty of establishing guidelines that adequately define a standard of care while addressing the range of variables that are inevitably involved in making individual medical judgments

Current State of Guidelines:

The closest thing we have to national guidelines – and they are a long way from what would be needed to establish a standard of care -- are those included in the National Guideline Clearinghouse (www.Guidelines.gov), an initiative of the Agency for Healthcare Research and Quality (AHRQ) within the Department of Health and Human Services. They currently contains over 2,400 clinical practice guidelines. AHRQ reviews each guideline submitted by professional organizations and posts those that are evidence-based. However, there are many guidelines within a disease category, and there is currently no process to endorse the "most effective or specific" or "most comprehensive" guidelines or to resolve conflicts among competing guidelines. The guidelines also leave room for interpretation, in part because they must be adapted to patients with multiple conditions and in part because it can be difficult to get provider consensus. In order to use the NGC guidelines to provide a legal standard of care, AHRQ would need considerable time and money to revise, streamline, standardize, integrate, and continuously update the guidelines. We believe professional medical societies and organizations should play a leading role in this effort, and achieving consensus will be quite difficult.

[3] A recent CBO report notes that the evidence of "defensive medicine" is "not conclusive, and whether limits on malpractice torts have an impact on the practice of medicine has been subject to some debate." *See* Congressional Budget Office, *Budget Options, Volume I, Health Care,* 21 (Dec. 2008). Recent studies also suggest that tort reform in states has not changed doctors' practices or reduced defensive medicine practices. *See, e.g.* Claudia H. Williams and Michelle M. Mello, "Medical Malpractice: Impact of the Crisis and Effect of State Tort Reforms," Robert Wood Johnson Foundation (May 2006).

2. Early Disclosure of Medical Errors and Mediation (MEDiC)

Under this model, included in the MEDiC bill you introduced in the Senate in 2005, health care providers, insurers, or health care systems would disclose adverse events, apologize, and adhere to a rigorous protocol.[4] This includes:

- Reporting to a patient safety officer any medical error, patient safety event, or failure to adhere to a standard of care, and if necessary, conducting a root cause analysis;
- Confidentially disclosing an incident if there is a patient injury or a failure to adhere to the standard of care, and offering the patient (1) an apology; and (2) fair compensation or offer to negotiate fair compensation; and
- Applying a percentage of the achieved savings from lower administrative and legal costs to the reduction of insurance premiums for doctors and to initiatives that will improve patient safety and/or reduce medical errors.

If the parties cannot reach a compensation agreement through mediation, the patient may still seek legal recourse. (However, the patient cannot use the provider's disclosure as an admission of guilt in any litigation.) To encourage providers to use this information to improve the quality of care, the Department of Health and Human Services would establish a patient safety and health care quality office and create a national database of patient-safety data to determine performance standards and best practices and to provide technical assistance to these programs nationwide.

Evidence: Many of the providers across the country that have adopted this program – notably, the University of Michigan Hospital system, Stanford Medical Center, Children's Hospitals and Clinics of Minnesota, and the VA Hospital in Lexington, Kentucky – have experienced fewer malpractice suits, decreased litigation costs, accelerated compensation to patients, and an increase in the numbers of patients who receive some compensation for their injuries.

Legislative Efforts: Obama-Clinton MEDiC Bill, Enzi-Baucus "Fair and Reliable Justice Act," and the Baucus White Paper. In Coburn-Burr "Patients' Choice Act," a state must encourage early disclosure of health care errors to receive a grant for medical malpractice reform.

Pros of MEDiC:

- Encourages disclosure and settlement rather than litigation
- May enhance patient safety if root cause analysis leads to changes in practice
- Some evidence of success in terms of reducing malpractice suits and litigation costs, accelerating compensation to patients, and increasing the number of patients who are compensated for their injuries in single institution pilot experiments (*e.g.* Rush Hospital in Chicago)

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[4] In your 2005 *New England Journal of Medicine* article on this proposal, you explained that the bill was responsive to studies that show "that the most important factor in people's decisions to file lawsuits is not negligence, but ineffective communication between patients and providers. Malpractice suits often result when an unexpected adverse outcome is met with a lack of empathy from physicians and a perceived or actual withholding of essential information. Stemming the causes of medical errors requires disclosure and analysis, which create tension in the current liability climate." Barack Obama and Hillary Clinton, "Making Patient Safety the Centerpiece of Medical Liability Reform," New England Journal of Medicine (May 2006).

Cons of MEDiC:

- Non-binding and may not be responsive to physicians' concerns/perceptions about liability
- Skepticism is commonplace among doctors, patients, and litigators
- Some resistance from doctors because it makes them feel guilty (but the AMA has indicated that they favor MEDiC-like proposals)

3. Pre-Trial Administrative Screening Panels

This option requires submission of medical malpractice cases to an administrative screening panel to determine whether the cases are frivolous or unsubstantial. The panel could include medical experts, legal experts, and/or community representatives. The panel's determination is non-binding, and either party may seek a trial de novo following the administrative proceeding.[5]

Evidence: At least 20 states have medical screening panels, and research concludes that screening panels have had no impact on claims payouts, no decrease in number of claims, and an equivocal impact on liability premiums. Experiences from Cook County, Illinois, where screening is required, corroborate these findings.

Legislative Efforts: Wyden-Bennett "Healthy Americans Act"

Pros of Screening Panels:

- Theoretically may decrease lawsuits, especially frivolous ones (although evidence to date shows no effect)

Cons of Screening Panels:

- Decision is admissible under state evidentiary law in a majority of states, which may create disincentives to full disclosure of errors and cause the plaintiffs' bar to view this as infringing on a patient's right to a jury by unfairly influencing the jury
- May actually increase the cost of litigation of medical negligence cases by adding additional step (and unclear who would pay for screening panels)
- Difficult to ensure that panels effectively play a "gatekeeper" role
- Idea of "gatekeeper" may be offensive to general view that access to the courts is a hallmark of our system of justice and that judges already have tools to weed out frivolous claims

4. Alternative Dispute Resolution

This option requires that all medical malpractice cases go through an alternative dispute resolution mechanism (ADR) before coming to trial. The mechanism could be mediation, arbitration, or some other dispute mechanism. Following completion of ADR, plaintiffs would be free to file suit in state courts.

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[5] This option therefore does not infringe upon the federal right or some state constitutional rights to a jury trial. But in a few instances, legislation mandating non-binding pre-trial screening has been struck down as unconstitutional in state court. Those decisions generally rested on state and federal equal protection grounds, with the courts arguing that treating victims of medical negligence differently from victims of other types of negligence violated equal protection.

Evidence: According to a survey by the Robert Wood Johnson Foundation, 15 states allowed ADR to resolve medical malpractice claims. Evidence suggests that ADR decreases the litigation rate and average awards. However, there is conflicting evidence concerning the effect of ADR on overall costs (when used voluntarily, ADR has been found to reduce costs). The use of court-ordered mediation does not have a significant impact on trial rates or speed of resolution of medical malpractice cases.

Legislative Efforts: Wyden-Bennett "Healthy Americans Act" and part of Obama-Clinton MEDiC bill

Pros of ADR:
- Potentially rapid resolution, if it performs similarly to workers compensation system
- May decrease lawsuits to the extent litigants accept resolution
- ADR does not need to be exclusive, and it can be used in combination with any of the other alternatives

Cons of ADR:
- May not generate significant change in physician psychology or behavior
- Could add expense and unclear who would bear the additional costs

5. Health Courts/Expert Panels

This option creates specialized administrative tribunals that have expertise in adjudicating medical disputes. Most health court proposals award compensation under the "avoidability" standard, which requires that claimants show that the injury would not have occurred if best practices had been followed, rather than a negligence standard. The courts would hire their own medical experts and develop decision guides for judges for common injuries as well as a uniform schedule of compensation. Complex cases or cases involving uncertainty could go to a full trial in front of an administrative judge with specialized medical expertise. Patients could appeal the decision to a higher level administrative tribunal, and potentially to a judicial court.

Evidence: Although health courts have been tried in several states – including Massachusetts, Virginia, Pennsylvania, Utah, Colorado, and Maine – the purported benefits are largely unproven. Estimates of the costs of health courts in Utah and Colorado have been revenue neutral compared to traditional tort litigation, but there is no information on overall costs in other states. Health courts have been found to reduce administrative costs and provide more standardized, lower compensation rates on average. However, because they increase the number of claimants five to ten fold, the overall costs are no different from tort claims.

Legislative Efforts: Baucus-Enzi "Fair and Reliable Medical Justice Act" in the 109th Congress, the Baucus White Paper, and Coburn-Burr "Patients' Choice Act"[6]

Pros of Health Courts/Expert Panels:
- Create uniformity and consistency in malpractice awards
- May increase accessibility and transparency for injured patients

[6] These start with "demonstration grants" that incentivize states to experiment with health courts, as proposed by even the most vocal academic and policy advocates for health courts.

- May reduce administration costs (although with an increase in claimants, often no change in overall costs)

Cons of Health Courts/Expert Panels:
- Heavy resistance in the legal community because they are viewed as supplanting jury trial right and ability to achieve fair and timely trial
- Costly on the front end and could actually end up increasing costs to the government
- Operationally complex, particularly if implemented in a widespread manner
- No evidence of strong support in the medical community

Next Steps

Given the sensitivity of this issue, we have not done the stakeholder or Hill outreach that would be necessary to develop and promote any medical malpractice policy. Two follow-up questions are:

- Which of these options would you like us to research further?

Conduct Further Research on:

___ Safe Harbor

✓ Early Disclosure of Medical Errors and Mediation (MEDiC)

___ Pre-Trial Administrative Screening Panels

___ Alternative Dispute Resolution

___ Health Courts/Expert Panels

- Would you like us to review any of these options with stakeholders and/or the Hill? (If "yes," we recommend our first step be a discussion with Senator Reid to determine how adverse the consequences might be for health reform in the Senate, and whether there are ~~modest~~ avenues he might be willing to support – *e.g.*, state demonstration projects.)

✓ Approve ___ Approve as amended ___ Disapprove ___ Discuss

Obviously we shouldn't do anything that weighs down the overall effort – but if this helps the team stay on board, we should explore it.

Appendix: Summary Table of Medical Malpractice Options

	Impact on:		
Policy	**Premiums / payouts**	**Number of claims**	**Clinical quality**
Safe Harbor [6]	• No net effect	• No net effect from small pilot projects to date	• Unknown – hypothesis is a large positive effect (e.g., HIT adoption, care based on guidelines)
MEDIC [1,3]	• Modest reductions in both payout and premiums	• Modest reduction	• Modest positive effect (e.g., root cause analyses)
Screening panels [3,7,8,9]	• No net effect	• Small reduction	• No effect
Alternative dispute Resolution [2,4]	• Modest reductions in payouts and premiums as part of more comprehensive program	• Cannot determine by itself	• No net effect from ADR itself
Health Courts [4,5]	• No net effect	• 5-10x increase in number of claimants compensated	• No effect
Caps [2,5]	• Mixed; slight reductions except Texas had a 30% decline	• No effect	• No effect

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